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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/585,884	11/20/2006	Yasuo Iwadate	50026/059001	4667

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EXAMINER	
WILSON, MICHAEL C	
ART UNIT	PAPER NUMBER
1632	

NOTIFICATION DATE	DELIVERY MODE
03/06/2008	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patentadministrator@clarkelbing.com

Office Action Summary	Application No.	Applicant(s)	
	10/585,884	IWADATE ET AL.	
	Examiner	Art Unit	
	Michael C. Wilson	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 December 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-10* is/are pending in the application.

4a) Of the above claim(s) *7-10* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-6* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *4-3-07,4-9-07,7-16-07,1-22-08*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-10 are pending.

Election/Restrictions

Applicant's election without traverse of Group I, claims 1-6, in the reply filed on 12-19-07 is acknowledged.

Claims 7-10 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 12-19-07.

Claims 1-6 are under consideration.

Claim Rejections - 35 USC § 112

Claims 1-6 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a method of treating a brain tumor comprising intracerebrally administering a Sendai viral vector (SeVV) lacking both the M and F genes to a mammal having a brain tumor, wherein the SeVV encodes IL-2 operably linked to a promoter, does not reasonably provide enablement for treating any tumor using any minus-strand RNA viral vector encoding any cytokine or further immunizing with a tumor antigen or vector expressing the antigen other than with an irradiated whole tumor cell of the same kind as the tumor, wherein the tumor cell expresses a tumor antigen. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

Claim 1 is drawn to a method of anti-tumor treatment comprising administering a minus strand RNA vector encoding an immunostimulatory cytokine or a cell into which the vector has been introduced. Minus strand RNA vectors encompass:

"…Sendai virus, Newcastle disease virus, mumps virus, measles virus, respiratory syncytial virus (RS virus), rinderpest virus, distemper virus, simian parainfluenza virus (SV5), and human parainfluenza viruses 1, 2, and 3 belonging to Paramyxoviridae; influenza virus belonging to Orthomyxoviridae; and vesicular stomatitis virus and rabies virus belonging to Rhabdoviridae.

Further examples of virus that may be used in the context of the present invention include those selected from the group consisting of: Sendai virus (SeV), human parainfluenza virus-1 (HPIV-1), human parainfluenza virus-3 (HPIV-3), phocine distemper virus (PDV), canine distemper virus (CDV), dolphin molbillivirus (DMV), peste-des-petits-ruminants virus (PDPR), measles virus (MV), rinderpest virus (RPV), Hendra virus (Hendra), Nipah virus (Nipah), human parainfluenza virus-2 (HPIV-2), simian parainfluenza virus 5 (SV5), human parainfluenza virus-4a (HPIV-4a), human parainfluenza virus-4b (HPIV-4b), mumps virus (Mumps), and Newcastle disease virus (NDV). A more preferred example is a virus selected from the group consisting of Sendai virus (SeV), human parainfluenza virus-1 (HPIV-1), human parainfluenza virus-3 (HPIV-3), phocine distemper virus (PDV), canine distemper virus (CDV), dolphin molbillivirus (DMV), peste-des-petits-ruminants virus (PDPR), measles virus (MV), rinderpest virus (RPV), Hendra virus (Hendra), and Nipah virus (Nipah)." (pg 12, lines 15-32).

Claim 1 encompasses administering the vector or any cell comprising the vector. The cytokine in claim 1 encompass any interleukin, cytokine or growth factor. Claim encompasses treating any tumor by administering the vector by any mode of administration.

The state of the art of gene therapy was that the combination of vector, promoter, dosage, cells, target tissue, level of expression and route of administration would provide a therapeutic or prophylactic effect using in vivo or ex vivo gene therapy (Miller 1995, FASEB J., Vol. 9, pg 190-199; pg 198, col. 1; Deonarain, 1998, Expert Opin. Ther. Pat., Vol. 8, pg 53-69; pg 53, 1st ¶, pg 65, 1st ¶ under Conclusion section; Verma,

Sept. 1997, Nature, Vol. 389, pg 239-242; see entire article, specifically pg 240, sentence bridging col. 2 and 3; Crystal, 1995, Science, Vol. 270, pg 404-410, pg 409; Ross, Sept. 1996, Human Gene Therapy, Vol. 7, pg 1781-1790; pg 1782, col. 2, 1st full ¶; pg 1789, col. 1, 1st ¶, all of record). The specification does not provide the combination of vector, promoter, dosage, level of expression that would result in a therapeutic/prophylactic effect.

The specification suggests various minus strand RNA vectors, various routes of administering vectors, various cytokines and various tumors. The specification does not teach the amount of cytokine expression that that treats cancer as claimed other than IL-2. The specification does not teach how to target tumor tissue other than intracerebral administration for treating a brain tumor. The specification does not teach how to target cytokine expression to tumors otherwise. The specification does not teach any minus strand RNA vector other than SeVV that provide adequate expression for treating tumors. In fact, the specification does not teach any SeVV other than one lacking both the M and F genes capable of treating cancer. Overall, the specification fails to teach the specific combination of vector, promoter, dosage, target tissue, level of expression and route of administration that would treat a tumor using gene therapy other than treating a brain tumor comprising intracerebrally administering a Sendai viral vector (SeVV) lacking both the M and F genes to a mammal having a brain tumor, wherein the SeVV encodes IL-2 operably linked to a promoter.

The amount of experimentation required to fill in the gaps left by the specification to use a minus strand RNA vector to treat tumor as broadly claimed would be undue.

The specification leaves those of skill to experiment whether SeVV with both the M and F genes can actually be used to treat cancer, what routes of administration target a tumor and provide anti-tumor expression levels, and what cytokines treat what types of tumors. The specification leaves those of skill to determine the specific combination of vector, promoter, and dosage required to treat tumors as broadly claimed.

Claim 2 requires a further step of immunizing with a tumor antigen or a vector encoding a tumor antigen. The specification is limited to subcutaneously administering irradiated whole tumor cells that are analogous to the tumor (pg 31, line 36). The amount of experimentation required to fill in the gaps left by the specification to use any tumor antigen or vector encoding a tumor antigen such that the tumor antigen is presented by an antigen presenting cell so that it "immunizes" as claimed. Therefore, claim 2 should be limited to subcutaneously administering irradiated whole tumor cells.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1 and 5 are rejected under 35 U.S.C. 102(e) as being anticipated by Kai (US Patent 6,514,728).

Kai administered a Sendai vector encoding INF-gamma to treat tumors (Example 1, paragraph bridging col. 5 and 6).

Claims 1 and 5 are rejected under 35 U.S.C. 102(b) as being anticipated by Bitzer (J. Gene Medicine, 2003, Vol. 5, pg 543-553).

Bitzer taught administering a Sendai virus vector (SeVV) encoding IL-10 to the airway of a mouse, a SeVV encoding FGF-2 to the muscle of a mouse, SeVV encoding IGF-1 to the muscle of a rat, SeVV encoding FGF-2 to synoviocytes of a rat or a SeVV encoding FGF-1 to the lateral ventricle of the brain of a rat (pg 548, Table 2). The phrase "anti-tumor treatment" is an intended use and does not bear patentable weight because it does not alter the steps of the method which are limited to administering a minus strand RNA viral vector. The claim does not require administering the vector to a patient having a tumor. Claim 5 is included because it limits "the tumor" of claim 1, however, claim 1 does not require administering the vector to a patient with a tumor.

Claims 2-4 are free of the prior art because the art at the time of filing did not reasonably teach or suggest administering a minus-strand RNA viral vector encoding an immunostimulatory cytokine or a cell into which the vector had been introduced further comprising immunizing with a tumor antigen or vector encoding a tumor antigen.

Claim 6 is free of the prior art because the art at the time of filing did not reasonably teach or suggest administering a minus-strand RNA viral vector encoding IL-2 or a cell into which the vector had been introduced.

Conclusion

Inquiry concerning this communication or earlier communications from the examiner should be directed to Michael C. Wilson who can normally be reached at the office on Monday, Tuesday, Thursday and Friday from 9:30 am to 6:00 pm at 571-272-0738.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

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For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

If attempts to reach the examiner are unsuccessful, the examiner's supervisor, Peter Paras, can be reached on 571-272-4517.

The official fax number for this Group is (571) 273-8300.

Michael C. Wilson

/Michael C. Wilson/
Patent Examiner